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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,322	08/22/2001	Phuong Grace Dang	452005-13	1448

27162 7590 01/15/2004

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,322	DANG ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 15-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 15-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Request for Continued Examination, Extension of Time, and Amendment C received on October 30, 2003 is acknowledged. Claims 1-6 and 15-30 are pending in this application.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denick et al (4,758,424) in view of JP 64007786.

Denick et al teach a chewable cough tablet containing guaifenesin (100mg) and pharmaceutical excipients. See example 5.

Denick et al do not teach the incorporation of carbetapentane tannate.

JP teaches the use of carbetapentane tannate as a non-irritant cough suppressor.

It would have been obvious to one of ordinary skill at the time the invention was made to combine the teaching of Denick et al and JP and further incorporate carbetapentane tannate. One would be motivated to do so since JP teaches that

carbetapentane tannate is a cough suppressor and Denick teaches a cough tablet. Therefore, one would be motivated to add a second cough agent to provide an additive effect since both drugs are taught to be cough agents and are utilized in the art for the same purpose.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/22762 by itself or in view of Chopdekar et al (5,663,415).

WO teaches a taste-masked pharmaceutical composition. Example II teaches a syrup composition containing 0.1323% dextromethorphan HBr, 1.3230% guaifenesin, and other pharmaceutical excipients. Examples of antitussives taught are dextromethorphan, cholpendianol, carbetapentane, etc. and their salts. See page 4, lines 24-29. The reference also teaches the method of reducing or abating the symptoms associated with the common cold, respiratory disorders, etc. see page 1, lines 33-36. WO teaches tablets or liquid dosage forms. See page 5, lines 25-27.

WO does not exemplify the inclusion of carbetapentane tannate.

Chopdekar et al teach antihistamine tannates since this form is stable and may be administered in its form without any side effects. See column 1, lines 15-18. The antihistamine reacted with the tannic acid may be carbetapentane, among others. See column 3, line 3.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to substitute dextromethorphan with carbetapentane in WO's example II. One would be motivated to do so with the expectation of similar results since WO teaches that both dextromethorphan and carbetapentane are antitussives. Therefore, it

is deemed prima facie obvious to substitute one functional equivalent agent with another equivalent agent since both are known in the art for the same functional purpose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Chopdekar et al and utilize the tannate salt of carbetapentane. One would be motivated to do so since Chopdekar teaches the tannate salt form is more stable and has less side effects. Therefore, one would be motivated to use the tannate form to yield a stable composition with less side effects when the composition is administered. Further, one would expect similar results since WO teaches that the pharmaceutical acceptable salts of the antitussives are suitable for use in the composition.

Claims 15-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/22762 by itself or in view of Chopdekar et al (5,663,415) in further view of Sims et al (5164398).

WO teaches a taste-masked pharmaceutical composition. Example II teaches a syrup composition containing 0.1323% dextromethorphan HBr, 1.3230% guaifenesin, and other pharmaceutical excipients. Examples of antitussives taught are dextromethorphan, cholpendianol, carbetapentane, etc. and their salts. See page 4, lines 24-29. The reference also teaches the method of reducing or abating the symptoms associated with the common cold, respiratory disorders, etc. see page 1, lines 33-36. WO teaches tablets or liquid dosage forms. See page 5, lines 25-27.

Chopdekar et al teach antihistamine tannates since this form is stable and may be administered in its form without any side effects. See column 1, lines 15-18. The antihistamine reacted with the tannic acid may be carbetapentane, among others. See column 3, line 3.

The references do not teach the dosage range of the antitussive.

Sims et al teach a pharmaceutical composition containing an analgesic, an antitussive, and expectorant for the relief of cough and cold symptoms (co. 1, lines 30-65). Sims teaches dextromethorphan or carbetapentane or its salt including tannate as the antitussive agent (col. 2, line 39). Guaifenesin is taught as one of the expectorants that can be used. Sims teaches the composition in the form of a tablet or suspension (col. 3, lines 40-41). The antitussive is utilized in the amount of 1-50 mg depending on the specific antitussive used and the expectorant in the amount of 100-1000 mg. See column 3, lines 30-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Sims teachings and utilize the instant dosage ranges. One would be motivated to utilize the instant ranges since Sims teaches this is the suitable and conventional range of the cough agents in cold remedy formulations.

In regards to the method of administering the tablets twice-a-day, it is deemed obvious to one of ordinary skill in the art to effective dosage amount by either administering the entire one-day dosage of the medication at one time or dividing it into multiple dosages since the criticality lies in administering the "effective and maximum" dosage rather than how many times it is administered. Further, note that in the

composition claims, the preamble "twice-a-day therapeutic composition" is not given patentable weight since it is intended use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147 or (571) 272-0614 after February 2, 2004. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927 or (571) 273-0614. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG
January 5, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER